

(DRG - 11/70)

## REVIEW PROCEDURES

### I. CONFIDENTIAL NATURE OF INFORMATION

Proceedings of review meetings are regarded as privileged communication and are prepared only for use by consultants and the staff and should not be filed in libraries, whether Government or non-Government. Under no circumstances should consultants advise applicants of recommendations. Premature advice to the applicant may prove embarrassing to all concerned and be a distinct disservice to the applicant who may have been led into unwise actions on the basis of erroneous information.

### II. REVIEW OF APPLICATIONS

To avoid situations of possible conflict of interest, members of advisory groups have traditionally followed the practice of absenting themselves from the meeting room when applications submitted by their own institutions are being discussed. In the case of State higher education or other similar systems, where the multiple campuses are geographically separated, the term "own institution" is intended to mean the separate single organization of which the member is an employee, consultant, or has a financial interest. This permits the member to be present during the action taken on an application from any institution included in the member's university system except his own, unless in his judgment a conflict of interest situation obtains. As a further step to protect consultants from allegations of possible favoritism, no application will be assigned for initial review by the advisory group of which the principal investigator, program director, candidate, or sponsor is a member. In unusual circumstances, this requirement may be waived by the Bureau Chief.

### III. STUDY SECTION RECOMMENDATIONS

The Study Section's recommendation is made by majority vote of its members. If the Council/Committee concurs, the Institute/Division staff advises the applicant of the recommendation, but it gives reasons only when asked to do so by the Study Section or by the applicant. The Study Section may suggest communication to the applicant along with its recommendation of approval or disapproval. The following recommendations are to be used:

#### A. APPROVAL

The application meets the criteria of the Study Section for scientific merit. This recommendation can be for the budget and time requested, or for an increase or decrease in budget and/or time. A priority rating is required.

B. DISAPPROVAL

The application (project, investigator, resources, and/or environment) does not meet the criteria of the Study Section for scientific merit. The Study Section may also recommend disapproval when it believes that potentially hazardous or unethical procedures are involved\* or that, for reasons other than scientific merit, no funds should be recommended (e.g., an unnecessary supplement).

C. DEFERRAL

The information available is not adequate to permit a recommendation of approval or disapproval. The Study Section defers the application for a project site visit or for other additional information.

IV. POTENTIALLY HAZARDOUS PROCEDURES AFFECTING HUMAN SUBJECTS

Safeguarding the rights and welfare of human subjects involved in research is the responsibility of the institution to which support is awarded. In order to provide for the adequate discharge of this responsibility, the Public Health Service requires (1) assurance from each of these institutions that it has established adequate initial and continuing review procedures for such research, and (2) certification of the completion of the initial review of each project. However, the acceptance by institutions of the prime responsibility for protecting human subjects does not relieve Public Health Service review groups and consultants from the responsibility for identifying doubtful situations and recommending disapproval if the proposed research procedures remain unacceptable despite review and approval by the institution.

In the course of review of proposals, PHS review groups, both initial and final, should apply ethical standards uniformly regardless of the certification status of the proposal or its state or country of origin. Review groups may (a) recommend approval without restrictions when the subject's rights and welfare are not infringed; (b) recommend approval but identify concerns to be communicated to the institution sponsoring the research; (c) recommend approval contingent on restrictions affecting or eliminating areas of concern involving human subjects; or (d) recommend disapproval if the hazards are so grave as to be unacceptable.

## V. NUMERICAL RATING PROCEDURE

Those applications recommended for approval by a majority vote of the Study Section should be rated on the basis of scientific merit from 1.0 (most meritorious) to 4.5 (least meritorious) using 0.5 intervals only. The priority rating given should pertain to the recommended, not the requested, budget and time. In the case of a split vote, all members must record a rating; the rating of 5.0 may (but need not necessarily) be used by those members who recommend disapproval.

The ratings should be based on evaluation of the merit of a proposal in relation to the "state of the art" of its particular research area. Some of the factors to be considered in assigning ratings are study design, originality, competency of the investigator, and adequacy of the facilities and working environment.

In rating an application that has been recommended for approval, please consult the illustrative graph on the next page.

The rating activity, although subject to human error, may be made more reliable if the raters are cognizant of such pitfalls as:

- (a) the Halo Effect, in which ratings may be based on general impressions rather than on critical evaluation of each relevant aspect of the proposal;
- (b) the Logical Error, which is related to the Halo Effect, but which involves the possible error of assuming correlations between separate aspects of a given proposal where none actually exists;
- (c) the Error of Leniency, in which raters may judge investigators and/or proposals more favorably ("easy" raters) or less favorably ("hard" raters) because of personal involvement and/or greater familiarity with a particular research area; and
- (d) the Error of Central Tendency, in which raters may hesitate to employ the extreme values of a scale and thus tend to rate applications in the directions of the mean of the total group of applications.

# PRIORITY RATING SCALE

